APR 17 2007

# 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

**1) Submitter's name, address, telephone number, contact person:**

Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116
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Regulatory Affairs Consultant
Telephone: (510) 388-5001
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Prepared February 17, 2007

**2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

INTERSON USB Ultrasound Probe System

Classification Names:

| | CFR Number | Product Code |
|---|---|---|
| Ultrasound Pulsed Echo Imaging System | 892.1560 | 90-IYO |
| Diagnostic Ultrasound Transducer | 892.1570 | 90-ITX |

**3) Identification of the predicate or legally marketed device:**

Interson Corporation believes that INTERSON USB Ultrasound Probe System is substantially equivalent to the currently marketed Terason 2000.

**4) Device Description:**

The Interson USB Ultrasound Probe System is a self contained portable, multiple-mode, and multiple-application ultrasound imaging system. The system contains an ultrasound generator/receiver, analog to digital converter, microcontroller, control logic, USB 2.0 interface and control offering a full complement of conventional operating modes, software-based parameter controls, and recording. The selection eight transducers to be offered with the system permits a wide range of clinical applications including fetal heart, abdomen, OB/GYN, vascular, extremity, pediatric, cardiac, neonatal cephalic, urology, ophthalmology. With these general areas of intended use, the various transducers adapt the system for the specific imaging tasks.

Eight different models of the USB Ultrasound Probe System are available and any two may be connected at the same time to a USB 2.0 port. In addition to the initial operational settings for each USB Ultrasound Probe System are preprogrammed in the system. User-customized parameter settings for each USB Ultrasound Probe System may be inserted by the operator and stored for recall as needed via the system control panel. Customization includes transmit power, images controls selection, and Time Gain Compensation (TGC). Controls are also provided to select display format and to utilize the cine function.

More detailed explanations of these functions and controls are included in the Operator Manual, and in the software/firmware documentation included in this 510(k) Notification. Patient contact materials have been used in accordance to their intended use and are described below for each individual transducer. All of the transducers were previously cleared for use on other Systems,.

The Interson USB Ultrasound Probe System is a B-Mode scanner and supports a wide variety of applications. It is an ultrasound scanner, which provides high resolution, high penetration performance. Probes are supported in frequencies from 2.5 MHz to 12.0 MHz. These probes can be applied to a variety of fields such as fetal heart, abdomen, OB/GYN, vascular, extremity, pediatric, neonatal cephalic, cardiac, ophthalmology, and urology. The Interson USB Ultrasound Probe System provides various measuring functions. It can measure distances and calculate areas, circumferences and volumes, as well as calculate the date of delivery by using BPD (biparietal diameter), OFD (occipito-frontal diameter), HC (head circumference), AC (abdominal circumference), AD (abdominal diameter), FL (femur length), CRL (crown rump length), APTD (anteroposterior trunk diameter), TTD (transverse trunk diameter), GS (gestational sac), and LMP (last menstral period). Biopsy guidelines are provided on screen to assist in the collection of tissue samples, using biopsy guide adapters offered as an optional accessory. Operating Modes of Interson USB Ultrasound Probe System is B-Mode, The Interson USB Ultrasound Probe System supports the Cine function (capable of storing up to 32 to 512 sequential images). Management of patient history is possible by image-storage function. High-resolution images are provided by utilizing a technology called digital dynamic receive focusing. The same clinical uses were cleared for the predicate device(s), Teratech, Terason 2000, K992505

**5) Intended Use**:

- Fetal - OB/GYN
- Abdominal
- Small Organs (breast, thyroid, testicle)
- Pediatric
- Neonatal Cephalic
- Trans-Vaginal
- Trans-Rectal
- Peripheral Vascular
- Cardiac

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.
- Pediatric scans of organs, superficial, and bony structures.
- Monitoring procedures for infertility studies (other than in vitro fertilization).
- First, second and third trimester pregnancy studies.
- Neonatal head studies.
- Podiatry scans of superficial structures including muscles, tendons and bones.
- General cardiac studies in adults.
- Prostate, bladder and rectum visualization.

**6) Technological Characteristics:**

This device operates identical to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D images. Scanhead patient contact materials are biocompatible.

The device's acoustic output limits are:

All Applications:

| | | |
|---|---|---|
| $I_{SPTA.3}$ | 94 mW/cm2 | (Maximum) |
| MI | 1.9 | (Maximum) |

The limits are the same as predicate Track 1 devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Interson Corporation
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

APR 17 2007

Re: K070907
Trade Name: INTERSON USB Ultrasound Probe System
Regulation Number: 21 CFR §892.1560
Regulation Name: Utrasonic pulsed echo imaging system
Regulatory Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: Class II
Product Code: IYO and ITX
Dated: March 31, 2007
Received: April 2, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the INTERSON USB Ultrasound Probe System, as described in your premarket notification:

Transducer Model Number

OP 12.0 MHz
MV 12 MHz
GP 2.5 MHz
VC 7.5 MHz
EC 7.5 MHz
SF 7.5 MHz
SP 7.5 MHz
GP 5.0 MHz
GP 3.5 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D., at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

# SECTION 4.3

## INDICATIONS FOR USE

### Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B + M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | N | N | | | | | | | | |
| Fetal | | N | | | | | | | | Note 3 |
| Abdominal | | N | | | | | | | | Note 1 Note 3 |
| Intra-Operative (Specify) *(See note 4)* | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | N | | | | | | | | Note 3 |
| Small Organ | | N | | | | | | | | Note 3 Note 2 |
| Neonatal Cephalic | | N | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | N | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | N | | | | | | | | Note 3 |
| Trans-Vaginal | | N | | | | | | | | Note 3 |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | N | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | N | | | | | | | | |
| Muscular-Skeletal Superficial | | N | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N=new indication
Note 1: Abdominal, Solid organs, aneurysms.
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

David A. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** GP 2.5 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | N | | | | | | | | |
| Abdominal | | N | | | | | | | | Note 3 |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | N | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | N | | | | | | | | |
| Muscular-Skeletal Superficial | | N | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N=new indication
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

David A. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** GP 3.5 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | P | | | | | | | | |
| Abdominal | | P | | | | | | | | Note 3 |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | | | | | | | | Note 2 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

P=Previously Cleared, K951976
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

*Prescription Use* ✓

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** GP 5.0 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | P | | | | | | | | |
| Abdominal | | P | | | | | | | | Note 3 |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | | | | | | | | Note 2 |
| Neonatal Cephalic | | P | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | P | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

P=Previously Cleared, K951976
Note 2: Small Organ: breast, thyroid, testes.

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** SP 7.5 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | P | | | | | | | | Note 3 |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | | | | | | | | |
| Neonatal Cephalic | | P | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | P | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

P=Previously Cleared, K951976
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

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Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** SF 7.5 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | | | | | | | | Note 2 Note 3 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | P | | | | | | | | Note 3 |
| Trans-Vaginal | | P | | | | | | | | Note 3 |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | P | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

P=Previously Cleared, K951976
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** MV 12 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | N | | | | | | | | Note 2 Note 3 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | N | | | | | | | | Note 3 |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N=new indication;
Note 2: Small Organ: breast, thyroid, testes.
Note 3: Includes imaging for guidance of biopsy

Prescription Use ✓

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** EC 7.5 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | P | | | | | | | | Note 3 |
| Trans-Vaginal | | P | | | | | | | | Note 3 |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

P=Previously Cleared, K951976
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

David G. Lagzdins

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** OP 12.0MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | N | N | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | | | | | | | | | |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

N=new indication

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

David R. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907

## Ultrasound Device Indications For Use

**510(k) Number:** K070907
**Device Name:** INTERSON USB Ultrasound Probe System
**Transducer:** VC 7.5 MHz Mechanical Sector Probe

**Indications for Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

*Mode of Operation*

| Clinical Application | A | B | M | PWD | CWD | Color Doppler | Amplitude Doppler | Color Velocity Imaging | Combined (B - M) | Other (Specify) |
|---|---|---|---|---|---|---|---|---|---|---|
| Opthalmic | | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-Operative (Specify) | | | | | | | | | | |
| Intra-Operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ | | P | | | | | | | | Note 3 |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Transesophageal | | | | | | | | | | |
| Trans-Rectal | | | | | | | | | | |
| Trans-Vaginal | | | | | | | | | | |
| Trans-Urethral | | | | | | | | | | |
| Intra-Vascular | | | | | | | | | | |
| Peripheral -Vascular | | P | | | | | | | | Note 3 |
| Laparascopic | | | | | | | | | | |
| Muscular-Skeletal Conventional | | | | | | | | | | |
| Muscular-Skeletal Superficial | | | | | | | | | | |
| Others (Specify) | | | | | | | | | | |

P=Previously Cleared, K951976
Note 3: Includes imaging for guidance of biopsy

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use ✓

David A. Jegerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070907